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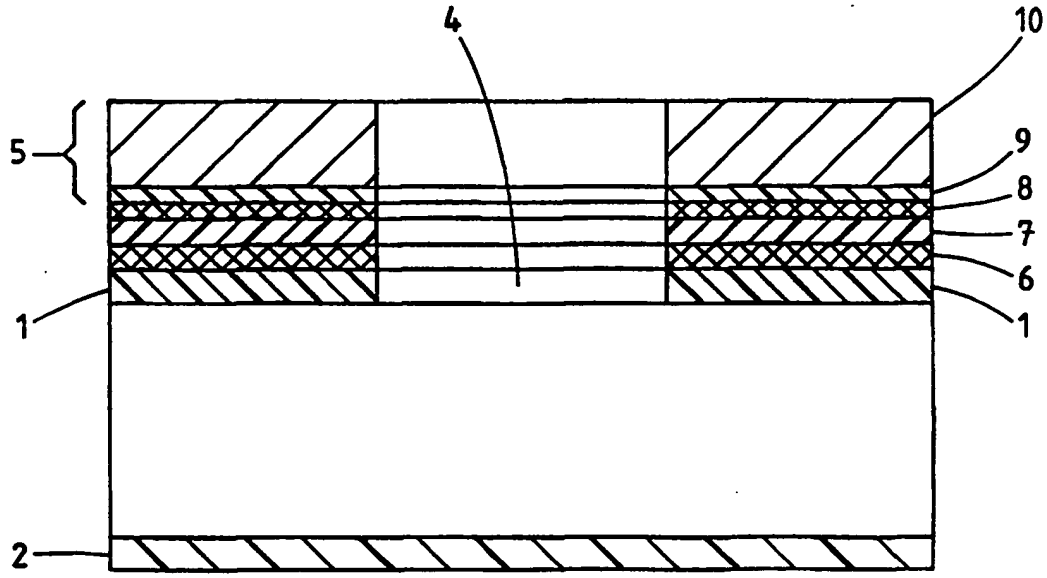

(57) Abstract

The invention provides a drainage bag, such as an ostomy bag or like drainage bag, for receiving bodily waste, the drainage bag having a wall portion (1) formed of a water-softenable or hot-water-soluble first film material, the wall portion (1) having an opening (4) therein for receiving the bodily waste or bodily fluid; a water-impermeable, water-insoluble polymeric film material (7) being adhered to the outer surface of the said wall portion (1) so as to surround said opening, the water-impermeable, water-insoluble layer (7) being adhered to the said wall portion by means of a cyanoacrylate layer (6) interposed therebetween; and the outer surface of the water-impermeable, water-insoluble layer (7) having secured thereto an adhesive flange (5) for securing the drainage bag to the body wall of a patient.

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OSTOMY BAGS

The present invention relates to laminar structures, and in particular ostomy bags incorporating such laminar structures.

Ostomy bags for receiving bodily waste from colostomy and ileostomy patients are well known and a major problem with such bags is that it can be difficult to dispose of the used bag in a convenient and hygienic manner. A known approach to this problem has been to make the ostomy bag from a material which degrades or dissolves in water and can therefore be flushed down a W.C. bowl after use. One material which has been employed for this purpose is a polymeric film formed from polyvinylalcohol/ polyvinylacetate (PVA). As is generally known, the water-solubility of a particular grade of PVA will depend upon the extent of hydrolysis of the ester groups in the polymer, the water solubility in general increasing with the number of free hydroxyl groups in the polymer. Thus it is possible to obtain grades of PVA which are readily soluble in hot water but remain insoluble over a period of several days (i.e. for the maximum time over which an

ostomy bag would normally be worn) in cold water. Such hot water-soluble grades of PVA can be used to form ostomy bag liners which have the advantage that over a more prolonged period, they are biodegradable.

However, although disposable ostomy bags formed of PVA have been found to perform well, it has also been found that it is somewhat difficult to provide a secure attachment between the PVA bag wall and the material of the adhesive flanges typically used to attach ostomy bags to the abdomens of patients. In particular, where moisture is allowed to come into contact with the PVA bag wall in the region of the bond between the PVA wall and the adhesive flange, the moisture has a tendency to destroy the bond, leading to the bag wall and adhesive flange becoming detached.

It is an object of the present invention to overcome or at least alleviate this problem.

It has now been found that by interposing a layer of a water-impermeable water-insoluble material between the PVA bag wall and adhesive flanges, and by bonding the water-impermeable, water-insoluble material to the PVA bag wall by means of a cyanoacrylate adhesive, the aforementioned problem can be overcome.

Accordingly, in a first aspect, the invention provides a drainage bag, such as an ostomy bag or like drainage bag, for receiving bodily waste, the drainage bag having a wall portion formed of a water-softenable or hot-water-soluble first film material, the wall portion having an opening

therein for receiving the bodily waste or bodily fluid; a water-impermeable, water-insoluble polymeric film material being adhered to the outer surface of the said wall portion so as to surround said opening, the water-impermeable, water-insoluble layer being adhered to the said wall portion by means of a cyanoacrylate layer interposed therebetween; and the outer surface of the water-impermeable, water-insoluble layer having secured thereto an adhesive flange for securing the drainage bag to the body wall of a patient.

The water-softenable or hot-water-soluble film is one which has negligible solubility at room temperature (25°C), is slowly soluble at around 38°C over a period of at least two days, but which disintegrates within less than 60 minutes, preferably less than 30 minutes at water temperatures in excess of 50°C.

The water-softenable or hot-water-soluble first film material is preferably a film formed from polyvinylacetate/polyvinylalcohol. One particularly suitable PVA film material is the 30μ thick PVA film marketed under the reference code EC600 by NEDI of Middlewich, Cheshire, UK. Such film dissolves or disintegrates within 30 seconds at 50°C in water, but at 38°C is only very slowly soluble, and at room temperature is reasonably stable. This particular film is not only soluble in hot water, but is also degraded by bacteria relatively quickly.

Further examples of suitable PVA films are the "BP 26 mic", "LA-60 25 mic" and "NP 40 mic" grades of PVA

film manufactured by The Aicello Chemical Company Limited, Aichi, Japan, the properties of which are given in Table 1 below.

TABLE 1

20°C, 60%RHO

Item	Tensile stir. (kg/mm2)		Elongation (%)		10% Young's Modulus		Impact strength at -10°
Grade	MD	TD	MD	TD	MD	TD	kg-cm (14° F)
BP 26 mic.	2.5 - 3.0	3.3 - 3.8	270 - 320	340 - 390	6.0 - 8.0	6.0 - 8.0	5.00
LA-60 25 mic.	3.1 - 3.6	3.1 - 3.6	280 - 330	300 - 350	7.0 - 9.0	7.0 - 9.0	7.00
NP 40 mic.	3.6 - 4.0	3.3 - 4.0	250 - 300	280 - 320	6.1 - 7.3	4.5 - 7.6	8.00

Temperature 20°C

The water-impermeable, water-insoluble polymeric film material is preferably selected from polyvinylchloride (PVC), polyvinyldichloride (PVDC), ethylene vinyl alcohol polymer (EVA) polyurethane, polyester, polyolefins such as polyethylene and blends and copolymers thereof.

Most preferably the water-impermeable water-insoluble polymeric film is formed from PVC.

In a further aspect the invention provides a laminar structure comprising a first film formed from a polyvinylacetate/polyvinylalcohol material and a second film formed from a water-impermeable, water-insoluble polymer as hereinbefore defined, the first and second films being bonded together by an intervening layer of cyanoacrylate.

The invention will now be illustrated but not limited by reference to the specific embodiments illustrated in the

accompanying drawings of which:

Figure 1 is a plan view of an ostomy bag according to one embodiment of the invention; and

Figure 2 is a sectional elevation along line I-I in Figure 1.

Referring now to the drawings it can be seen that the ostomy bag shown in Figures 1 and 2 is formed from two sheets 1,2 of a hot water-soluble grade of PVA bonded together by means of welding around their peripheries 3. A particular hot-water-soluble grade of PVA is the EC600 grade PVA referred to above. One of the sheets 1, has an opening 4 therein for fitting about the stoma of a patient and for receiving bodily waste from the stoma. The opening is surrounded by an adhesive flange 5 of known type which is used to adhere the ostomy bag to the body wall of a patient.

The construction of the joint between the PVA layer 1 and the adhesive flange 5 is illustrated in more detail in Figure 2. There it can be seen that the PVA layer 1 has bonded to its outer surface thereof by means of a cyanoacrylate adhesive layer 6 a layer of a water-impermeable, water-insoluble polymeric film 7. The polymeric film 7 may be selected from a number of polymers such as PVC and polyurethane, with PVC being particularly preferred. The cyanoacrylate adhesive may be, for example, Code 406 Instant Adhesive available from Loctite (UK) of Welwyn Garden City, UK.

Secured to the outer surface of the polymeric film 7,

by means of an adhesive layer 8 is the adhesive flange 5. Adhesive flange 5 may be of known type and, in this embodiment, has a backing film 9 formed of PVC, the outer surface of which is coated with a hydrocolloid adhesive 10 of known type.

An ostomy bag of the type illustrated may serve as an inner bag in a two-bag system of the type illustrated in our earlier Application WO 94/12128. In such an arrangement, the rear surface of the adhesive flange 5, i.e. the surface which in use faces away from the patient, may have detachably secured thereto an outer bag formed of a relatively tough waterproof material (not shown) such as PVC, polyvinyldichloride (PVDC) or ethylenevinylalcohol (EVA).

The advantage of the form of construction described above is that if water comes into contact with the PVA film in the region of the bond to the adhesive flange, it has been found that little or no deterioration in the integrity of the bond takes place. By contrast, it has been found that when other adhesives are used such as rubber resin adhesive, solvent and emulsion-based acrylic adhesives, polyvinylalcohol-based adhesives and starch-based adhesives, the presence of moisture can lead to the flange becoming detached from the bag when relatively little strain is placed on the bond.

Moreover, where adhesives rely upon a keying mechanism, e.g. hot-melt polyester-based adhesives, penetration of moisture into the interface between the

surface of the adhesive and the PVA film itself, causes bond failure.

It will readily be appreciated that numerous modifications and alterations may be made to the arrangements specifically illustrated in the accompanying drawings without departing from the principles underlying this invention. All such modifications and alterations are within the scope of this Application.

CLAIMS

1. A drainage bag, such as an ostomy bag or like drainage bag, for receiving bodily waste, the drainage bag having a wall portion formed of a water-softenable or hot-water-soluble first film material, the wall portion having an opening therein for receiving the bodily waste or bodily fluid; a water-impermeable, water-insoluble polymeric film material being adhered to the outer surface of the said wall portion so as to surround said opening, the water-impermeable, water-insoluble layer being adhered to the said wall portion by means of a cyanoacrylate layer interposed therebetween; and the outer surface of the water-impermeable, water-insoluble layer having secured thereto an adhesive flange for securing the drainage bag to the body wall of a patient.

2. A drainage bag according to Claim 1 wherein the hot-water-soluble first film material is polyvinylacetate/polyvinylalcohol.

3. A drainage bag according to Claim 1 or Claim 2 wherein the water-impermeable, water-insoluble polymeric film material is selected from polyvinylchloride, polyurethane, polyester, polyolefin, and blends and copolymers thereof.

4. A drainage bag according to Claim 3 wherein the water-

impermeable, water-insoluble polymeric film material is polyvinylchloride.

5. A drainage bag according to any one of Claims 1 to 4 wherein the adhesive flange comprises a backing layer of polyvinylchloride, the front surface of which is coated with a hydrocolloid adhesive material.

6. A laminar structure comprising a first film formed from polyvinylacetate/polyvinylalcohol, and a second film formed from a water-impermeable polymer, the first and second films being bonded together by an intervening layer of cyanoacrylate adhesive.

7. A laminar structure according to Claim 6 wherein the second film is formed from a polymeric material selected from polyvinylchloride, polyurethane, polyester, polyolefin, and blends and copolymers thereof.

8. A laminar structure according to Claim 7 wherein the second film is formed from polyvinylchloride.

9. A drainage bag substantially as described herein with reference to the accompanying drawings.

10. A laminar structure substantially as described herein with reference to the accompanying drawings.

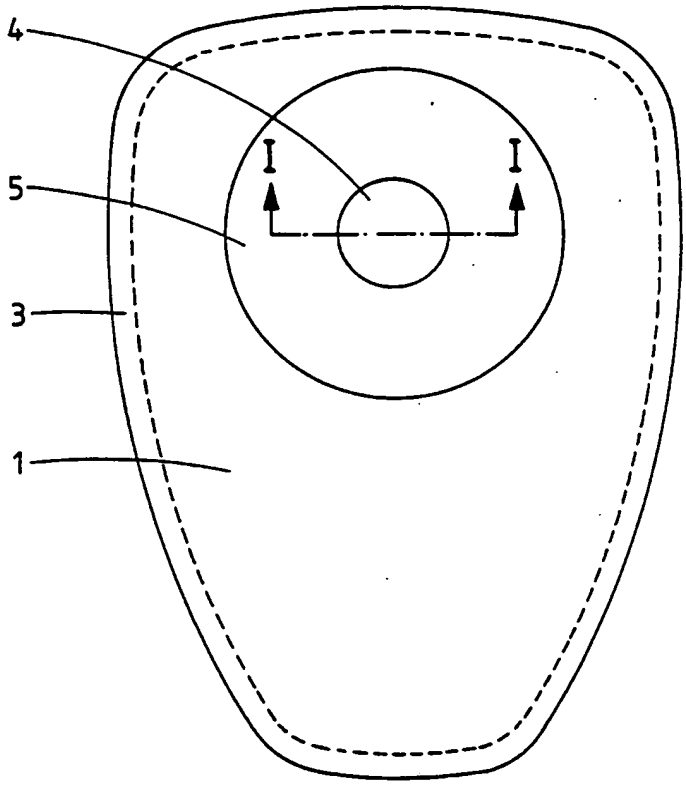

Figure 1

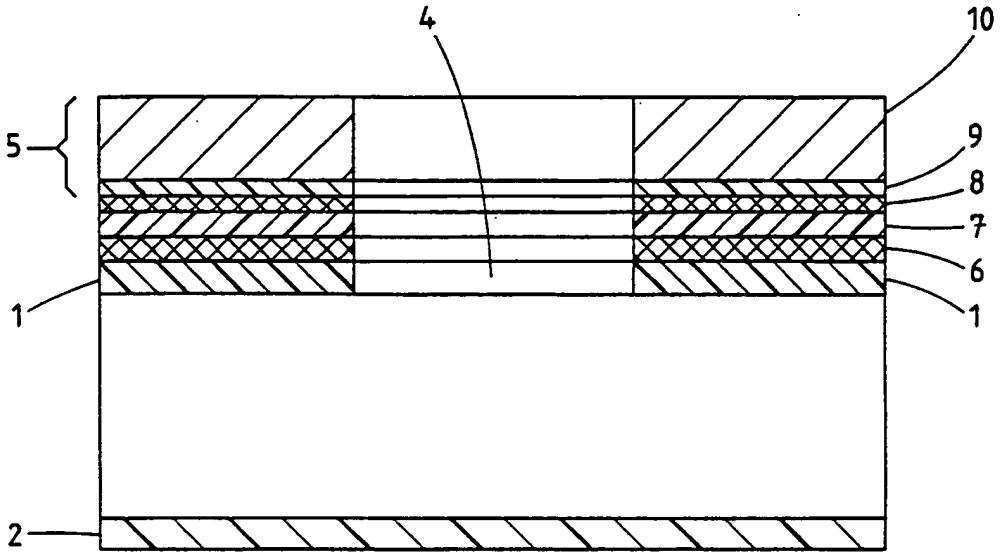

Figure 2

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/GB 95/01423

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F5/443 A61F5/448 B32B27/00 B32B7/00 A61L25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F B32B A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	FR,A,2 638 634 (SMITHS INDUSTRIES PLC) 11 May 1990 see page 3, line 31 - page 4, line 24	1
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[X] Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
30 October 1995	17. 11. 95

Name and mailing address of the ISA	Authorized officer
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

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